REMARKS

This amendment is intended as a full and complete response to the non-final Office Action dated April 8, 2008. In the Office Action, claims 8-28 are pending, of which claims 8-28 stand rejected. By this amendment, claims 8, 9, 13-17, 19, 23, 24 and 26-28 are amended, claims 10, 11 and 20-22 are canceled, new claims 29-34 are added, and claims 12, 18 and 25 continue unamended.

A. In the Specification:

The specification has been amended to provide minor grammatical corrections. Such grammatical corrections do not add any new subject matter to the application.

B. Examiner Interview:

A teleconference between Examiner Hao D. Mai, Examiner Wilson and the Applicant's representative, Steven M. Hertzberg, on June 25, 2008 is duly noted and appreciated. During the teleconference, proposed amendments to the claims and the relevancy of the cited prior art patents were discussed. Details of the topics discussed during the teleconference as set forth by the Examiner in the Interview Summary dated on July 1, 2008 are hereby acknowledged.

In view of the following discussion, it is submitted that none of the claims now pending in the application are indefinite, anticipated or obvious under the respective provisions of 35 U.S.C. §112, §102 and §103. Thus, it is believed that all of these claims are now in allowable form.

REJECTIONS

A. 35 U.S.C. §112

In the Office Action it is stated that Claims 16-19 stand rejected under 35 U.S.C. §112 as being indefinite. Claim 16 recites limitations to the treatment plan, which was not actively claimed. Claims 17-19 recite limitations to the cutting device, which was not actively claimed. The rejection is respectfully traversed.

1. Claim 16

Claim 16 has been amended to depend from new dependent claim 29, which recites a treatment plan in the body of the claim. In particular, new dependent claim 29 recites:

> The surgical guide of claim 8, further comprising a treatment plan including a CT-scan and three-dimensional images which characterizes a plurality of walls defining the maxillary sinus and maxillary bone structures of the patient, said plurality of walls having dimensions, shapes, and contours formed along surface portions of the walls that are unique to the patient. (Emphasis added).

It is submitted that new dependent claim 29 is not indefinite and fully satisfies the requirements under 35 U.S.C. §112 and is patentable thereunder. Accordingly, it is submitted that claim 16, which depends indirectly from claim 8 and recites additional features considered inventive, is not also indefinite and fully satisfies the requirements under 35 U.S.C. §112 and is patentable thereunder. Withdrawal of the rejection is respectfully requested.

2. Claims 17-19

Claims 17-19 have been amended to depend, either directly or indirectly from new claim 30. New claim 30 has been added to include a cutting device in the body of the claim. New claim 30 depends from independent claim 8. In particular, new dependent claim 30 recites:

> The surgical guide of claim 8, further comprising a cutting device configured to interact along the ledge of the window.

Claim 17 has been amended to depend from new claim 30. Claim 17, as amended, recites:

> The surgical guide of claim 30, wherein said cutting device is a bur comprising:
> an elongated shaft having opposing first and second ends, said first end configured for insertion into a rotary device;
> a cutting blade coupled to the second end of said shaft; and
> a depth guide extending transversely from said shaft and spaced a predetermined distance from a distal end of said cutting blade. (Emphasis added).

Accordingly, it is submitted that claim 17, which depends from new dependent claim 30, which in turn depends directly from independent claim 8, is not indefinite and fully satisfies the requirements under 35 U.S.C. §112 and is patentable thereunder. Furthermore, claims 18 and 19

depend from dependent claim 17 and recite additional features considered inventive. Accordingly, it is submitted that these dependent claims are not indefinite and fully satisfy the requirements under 35 U.S.C. §112 and are patentable thereunder. Withdrawal of the rejection is respectfully requested.

B. 35 U.S.C. §102

1. Claims 20 and 22

In the Office Action, it is stated that claims 20 and 22 are rejected under 35 U.S.C. §102 as being anticipated by US Patent No. 6,235,035 to Boukhris (hereinafter "the `035 patent").

Claims 20 and 22 have been canceled. Therefore, the rejection is now considered moot.

2. Claims 23 - 28

In the Office Action, it is stated that claims 23-38 are rejected under 35 U.S.C. §102 as being anticipated by US Patent No. 5,320,529 to Pompa (hereinafter "the `529 patent"). The rejection is respectfully traversed.

As a preliminary matter, we believe that it would be helpful to review the appropriate standard under 35 U.S.C. § 102 for analyzing the features of a claim with respect to the prior art. It is well settled that "[a]nticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim" (Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984)(citing Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)) (emphasis added). The cited reference fails to disclose each and every element of the claimed invention, as arranged in the claim.

Independent claim 23 recites:

> A method of performing sinus elevation surgery to penetrate a lateral wall of a maxillary sinus of a patient, comprising:
>
> providing a treatment plan having three-dimensional images which characterizes a plurality of walls defining the maxillary sinus and maxillary bone structures

> of said patient, said plurality of walls having dimensions, shape, and contours formed along surface portions of the walls that are unique to the patient; and
>
> providing a surgical guide for placement adjacent said lateral wall of the maxillary sinus, said guide having a three-dimensional window that defines a surgical field, said window being formed by a peripheral edge defining an elongated ledge and including surface contours that correspond to and align with the uniquely shaped contours formed along surface portions of the walls defining the maxillary sinus and maxillary bone structures of the patient based on said treatment plan. (Emphasis added).

Referring to FIGS. 5 and 8 of the present application, as the thickness of the maxilla varies the thickness of the ledge 810 of the window 808 of the guide 800 will also vary along the ledge. (See substitute specification, page 19, paragraph 0048). Since at least one of the plurality of walls exhibits resorption of the bone, the guide includes a three-dimensional window that is shaped and dimensioned to correspond to and align with the uniquely shaped contours formed along surface portions of the walls defining the maxillary sinus and maxillary bone structures of the patient. The emulated shape and dimensions of the window are based on results acquired during said treatment plan.

By contrast, the `529 patent discloses a providing a bore that is circular in shape and sized to receive a drill bit for boring a circular hole in the lower jaw bone of a patient. In particular, the `529 patent discloses:

> The apparatus according to the invention for directing a bur includes a jawbone model formed by a method of scanning the jawbone with computerized tomography and constructing a stereolithographic model including a radiopaque (marker) representing the inferior alveolar nerve. The apparatus also includes a means for locating and drilling a hole in the model to avoid the radiopaque marker and a simulated implant (implant analog) is placed into the hole. A holder is then placed into this implant analog and protrudes above this implant analog. Then a guide template is fabricated on the jawbone model including a bore formed around the holder so that when the template is now transferred and placed on the jawbone of the patient, a specifically designed drill is guided by the template bore into the jawbone along the same path as the hole in the model to avoid the nerve and forms a hole for receiving the actual implant and holder. (See the `529 patent, col. 2, line 58 to col. 3, line 7, and FIG. 5, emphasis added).

The `529 patent further discloses:

> FIG. 5 shows the completed guide template 16 which is now placed on the patient's lower jawbone 20, not model 10. Surgical guide ring 25a is placed into a bore 38 of template 16 to provide a guide for drill or bur 17 as it penetrates jaw 20. Bur 17 will follow the path of site 14 which was made during model surgery when the surgeon visualized the location of opaque marker 11d which represented nerve 11a, i.e., in a vertical plane which passes through the mental foramen and is generally perpendicular to the surface of the model above and/or below the mental foramen. (See the `529 patent, col. 5, lines 33-43 and FIGS. 3 and 5)

Accordingly, the `529 patent only discloses a surgical guide having one or more bores for guiding a bur along a single direction to form an equally sized bore in the jaw bone of a patient. That is, the bores of the Pompa guide are circular (i.e., symmetrical) in shape to (i) guide the drill (bur) into the jawbone in a fixed direction along a single axis (e.g., vertical or Z-axis) and (ii) receive the threaded implants. The surgical guide disclosed in the `529 patent is not suitable for performing a sinus elevation procedure because the surgeon will not be able to use the guide of the `529 patent as a tracing pattern with a bur to cut along the peripheral edge (i.e., elongated ledge) of the window along the X and Y axes, since the bore (i.e., window) of the `529 patent and the bur have equal diameters.

The Applicant's surgical guide is completely different from the surgical guide of the `529 patent, since the present invention includes a three-dimensional window being formed by a peripheral edge defining an elongated ledge and including surface contours that correspond to and align with the uniquely shaped contours formed along surface portions of the walls defining the maxillary sinus and maxillary bone structures of the patient based on said treatment plan. In other words, the window of the present surgical guide has an elongated ledge and surface contours that emulate the unique surface contours of the maxilla bone of an individual, as opposed to only a conventional circular bore. Further, the window of the presently claimed invention is necessarily sized larger than the cutting edge of the bur to thereby allow the surgeon to trace and cut the

mucosal flap along the elongated and contoured ledge of the window to expose the lateral wall of the sinus and maxilla.

Moreover, the `529 patent teaches away from the presently claimed invention. Specifically, the `529 patent discloses that:

> With the STA Generated Model, a replica of the maxillary sinus wall, nasal wall and [pterygoid] plates will be precisely replicated and as described in this invention, the operating surgeon can perform model surgery on a clear model and transfer that information to the guide template and follow the same method as described for precise and accurate placement into these sites. The ability to perform precise placement can actually result in a less significant surgical procedure. Many of these patients with a resorbed maxillary upper jaw would need a pre-implant surgery to graft or augment the area and then have a second procedure performed to place the implants. The graft and augmentation procedure may be avoided with the ability to place implants with the precision described herein. (See the `529 patent, col. 6, lines 36-51).

Accordingly, the `529 patent teaches that the disclosed surgical guide avoids having to use pre-implant surgery to graft or augment the bony area prior to performing the procedure for installing the implants. By contrast, the present invention includes providing a treatment plan and providing a surgical guide that includes a window being formed by a peripheral edge defining an elongated ledge and surface contours that correspond to and align with the uniquely shaped contours formed along surface portions of the walls defining the maxillary sinus and maxillary bone structures of the patient based on said treatment plan. The window has a peripheral edge shaped to correspond to and align with the contoured surface area of the maxillary upper jaw so that pre-implant surgery can be performed to graft the area of the bone that has resorbed to a condition not suitable for providing implants in the bone. Therefore, the `529 patent teaches away from, as well as fails to disclose each and every element of the claimed invention, as arranged in the claim.

As such, it is submitted that claim 23 is not anticipated and fully satisfies the requirements under 35 U.S.C. § 102 and is patentable thereunder. Furthermore, claim 24-28 depend from independent claim 23 and recite additional inventive features. As such, and for at least the same reasons discussed above, it is submitted that these dependent claims also fully satisfy the requirements under 35 U.S.C. § 102 and are patentable thereunder. Therefore, withdrawal of the rejection is respectfully requested.

C. 35 U.S.C. §103

1. Claim 21

In the Office Action, it is stated that claim 21 is rejected under 35 U.S.C. §102 as being anticipated by US Patent No. 6,235,035 to Boukhris (hereinafter "the `035 patent").

Claim 21 have been canceled. Therefore, the rejection is now considered moot.

2. Claims 8 - 15

In the Office Action, it is stated that claims 8-15 are rejected under 35 U.S.C. §103 as being obvious over US Patent No. 5,746,743 to Greenberg (hereinafter "the `622 patent"). The rejection is respectfully traversed.

Independent claim 8, has been amended to include features recited in dependent claims 10 and 11. Dependent claims 10 and 11 have been canceled. Independent claim 8, as amended, recites:

> Surgical guide for performing sinus elevation and penetrating a wall of a maxillary sinus of a patient, comprising:
>
> a curvilinear-shaped structure for placement adjacent said wall of the maxillary sinus, said curvilinear-shaped structure having a three-dimensional window for placement over a portion of said wall of the maxillary sinus to define a surgical field to perform the sinus elevation, said window being formed by a peripheral edge that defines an elongated ledge having a first thickness and at least a second thickness differing from the first thickness to correspond to thickness variations of a bony wall lateral to said maxillary sinus, the a peripheral edge further including differing surface contours that correspond to and align with uniquely shaped contours formed along surface portions of the wall defining the maxillary sinus and maxillary bone of the patient. (Emphasis added).

The mandibular retractor of the `622 patent teaches away from the presently claimed surgical guide, since the shape of the aperture 60 in the retractor is a symmetrical aperture that does not include (i) a window being formed by a peripheral edge that defines an elongated ledge having a first thickness and at least a second thickness differing from the first thickness to correspond to thickness variations of a bony wall lateral to said maxillary sinus; and (ii) differing

surface contours that correspond to and align with the unique shape, dimensions and contours formed along the surface of the walls defining the maxillary sinus and maxillary bone of the patient.

Referring to page 17, paragraph 0044 to page 18, paragraph 0045 of the present application discloses that:

> Referring now to FIG. 8, the surgical guide 800 is curvi-linear in shape and is sized and shaped to correspond to the upper jaw (maxilla) and sinus shape of a particular patient, as determined by the CT scan and 3-D imaging software previously administered to the patient. As illustratively shown in the drawing, the surgical guide 800 includes a curved lower portion 802 having an upper surface 804 adapted for positioning along the lower edge of the maxilla (alveolar ridge) or the upper teeth (e.g., molars). The curved lower portion extends in an upward direction to form a second portion 806 having an overall height "H" an, overall width "W", and an overall thickness or depth "D".
>
> The upward extending second portion 806 includes at least one orifice or window 808 illustratively having a somewhat rectangular shape. The peripheral edges of the window 808 form a ledge 810 that is used in conjunction with a bur (FIG. 4) for performing the osteotomy, as discussed below in further detail. The size and shape of the window 808, as well as the depth or thickness of the ledge 810 are formed to correspond with the results of the CT scan and 3-D imaging software used for planning the osteotomy for a particular patient, such that the lower portion of the ledge 810 is aligned with and conforms to the shape of the bony floor of the sinus cavity and coronal portion of the maxilla. (Emphasis added).

The `622 patent discloses:

> [A] mandibular retractor which is inserted into the patient's mouth and has a curvilinearly-shaped retractor blade to retract the cutaneous region away from the mandible laterally. The retracting blade has an aperture which allows surgical instruments to be inserted through an incision in the cutaneous region, through the aperture, and to the mandible. The retractor also has an arcuate distal portion which may be located under and behind the mandible. The retractor allows a surgeon to retract with one hand and view the surgical site by looking down in to the mouth. The surgeon's other hand is free to operate surgical instruments such as a drill or screwdriver. (See `622 patent, col. 3, lines 25-37).

The `622 patent is completely silent with regard to the varying thickness and shape of the aperture corresponding to and aligning with the shape and contours of the maxillary bone of a

patient. Rather, the `622 patent only discloses that the aperture 60 is sized to receive and allow a surgical device to extend therethrough. In particular, the `622 patent only discloses "[t]he retracting blade has an aperture which allows surgical instruments to be inserted through an incision in the cutaneous region, through the aperture, and to the mandible." (See the `622 patent, col. 3, lines 29-32).

Even if the retractor of the `622 patent could somehow be used to perform a sinus elevation procedure (and it is submitted that the retractor cannot be used without undue risk to the patient), it would require a surgeon to perform the surgery by approximating where the floor of the sinus is located, where the superior portion is located, as well as where the anterior wall and the posterior wall are located. In addition, the variable depth of the lateral wall of the sinus could only be accessed with the experience and visual sense of the surgeon, without exact measurements as to the varying thickness of the osteotomy as it moved along the x-y axis. Thus, the retractor of the `622 patent defeats the very purpose of the present invention.

The present specification describes in the Background of Invention section thereof, the deficiencies of prior art surgical devices and procedures, which is relevant to the mandibular retractor of the `622 patent. In particular, the present specification discloses:

> One of the technical difficulties encountered during this procedure is the inability of the operator to precisely locate the floor of the sinus as he prepares the osteotomy from an antero-posterior direction (along the X-Y axis). Since the floor of the sinus can elevate and descend variably as the osteotomy moves antero-posteriorly, it is impossible to visualize this course. Therefore, the osteotomy is generally prepared in a straight line higher than the highest point of the sinus floor. This guarantees penetration into the sinus floor since an osteotomy that is lower than the sinus floor at any point will simply penetrate into the maxillary bone and not into the sinus cavity. This would require adjustment by expanding the osteotomy superiorly (apically) in order to penetrate the sinus cavity. Obviously, the additional trimming of bone is traumatic and removes bone unnecessarily.
>
> Another error occurs if the osteotomy is placed too superior to the floor of the sinus. Very careful manipulation must then be effected in order to negotiate the remaining lateral wall of the sinus inferior to the osteotomy and to descend below the Schneiderian membrane in order to elevate it from the sinus floor. This technically

> difficult maneuvering of the instruments along two planes increases the risk of tearing the [Schneiderian] membrane and thus compromising the outcome of the graft. Otherwise, the osteotomy must be adjusted by expanding in an inferior direction. This would lead to additional trimming of bone and increase the risk of tearing the membrane during the expansion of the osteotomy. It is nearly impossible to visualize the variable course of the sinus floor as the osteotomy progresses antero-posteriorly. This inability to visualize the course of the sinus floor is the first difficulty encountered in the procedure. (See Clean-Version of Specification, paragraphs 0005-0006, emphasis added).

A surgeon who performed a sinus elevation procedure using the mandibular retractor disclosed by the `622 patent would inevitably subject a patient to the undesirable risks described above. Specifically, the linear edges of the aperture 60 of the retractor do not include varying thicknesses and differing surface contours that emulate the unique bone structure of the patient. Therefore, the retractor of the `622 patent can not be properly aligned adjacent to the lateral wall of the patient to perform the surgical procedure. By contrast, the presently claimed invention eliminates the aforementioned risks by providing a customized surgical guide that conforms to the unique shape and contours of the patient's maxillary bone.

As further described in the specification of the present application:

> [p]reviously, this procedure was performed merely with an approximation as to where the floor of the sinus was, where the superior portion was, as well as where the anterior wall and the posterior wall are located. In addition, the variable depth of the lateral wall of the sinus was accessed only with the experience and visual sense of the clinician without exact measurements as to the varying thickness of the osteotomy as it moved along the x-y axis. The proposed surgical guide eliminates all approximations of the osteotomy in the x-y axis as to the outline of the osteotomy, as well as along the Z axis as to the depth of the osteotomy so as to prevent any damage of overcutting into the Schneiderian Membrane, and thus enabling easy access into the sinus cavity as outlined by the treatment plan set forth utilizing 3-D imaging software from a CT scan of the patient's maxillary sinus. (See substitute specification, page 8, paragraph 0015).

Accordingly, the Applicant's surgical guide differs from the mandibular retractor of the `622 patent because the shape and dimensions of the surgical guide of the present invention are customized and unique for each patient, as opposed to being a standardized shape that is used for all patients. The shape and dimensions are determined based on a treatment plan, for example, utilizing a CT scan and 3-D imaging software to provide details of the patient's maxillary sinus

and bone structures. The three-dimensional window formed in the surgical guide is dimensioned and shaped to correspond to and align with the unique shape of the maxillary bone of a patient, as opposed to being shaped as a matter of design choice. Thus, the Applicant's claimed surgical guide can be properly aligned and secured laterally against the patient's maxillary bone to allow the surgeon to perform the procedure with minimal risk of collateral damage to the surrounding surgical areas (e.g., Schneiderian Membrane).

Accordingly, it is submitted that the `622 patent fails to disclose or suggest the claimed feature of "said curvilinear-shaped structure having a three-dimensional window for placement over a portion of said wall of the maxillary sinus to define a surgical field to perform the sinus elevation, said window being formed by a peripheral edge that defines an elongated ledge having a first thickness and at least a second thickness differing from the first thickness to correspond to thickness variations of a bony wall lateral to said maxillary sinus, the a peripheral edge further including differing surface contours that correspond to and align with uniquely shaped contours formed along surface portions of the wall defining the maxillary sinus and maxillary bone of the patient". Therefore, the `622 patent fails to disclose or suggest the present invention as a whole.

As such, it is submitted that claim 8 is not obvious and fully satisfies the requirements under 35 U.S.C. § 103 and is patentable thereunder. Furthermore, claims 9-15 depend, either directly or indirectly, from independent claim 8 and recite additional features thereof. As such, and for at least the same reasons discussed above, it is submitted that these dependent claims also fully satisfy the requirements under 35 U.S.C. § 103 and are patentable thereunder. Therefore, withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the amendment and discussion presented herein, it is respectfully submitted that the present Amendment responds to all of the issues raised in the Office Action. Thus, it is submitted that all of the claims are in condition for allowance. Accordingly, reconsideration of this application and its prompt passage to issue are earnestly solicited.

If, however, the Examiner believes that there are any unresolved issues in any of the claims now pending in the application, we respectfully request that the Examiner telephone Steven M. Hertzberg at (212) 885-9223 so that appropriate arrangements can be made for resolving such issues as expeditiously as possible.

The Commissioner is hereby authorized to charge any additional fees, or to credit any overpayment, due by reason of this Amendment to Deposit Account No. 01-0035.

All correspondence should continue to be directed to the address below.

Respectfully submitted,

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